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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/439,040	11/12/1999	JACOBUS J.M. VAN DONGEN	4222US	1168

7590 05/20/2003

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EXAMINER	
WILDER, CYNTHIA B	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/439,040	Van Dongen et al.
Examiner	**Art Unit**
Cynthia B Wilder	1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 11, 2003*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-9, 11, 12, and 16-29* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) *11, 12, and 22* is/are allowed.

6) ☒ Claim(s) *1-9, 16-21, and 23-29* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

FINAL ACTION

1. Applicant's amendment filed in Paper No. 25 is acknowledged. Claims 1, 2, 3, 11, 12, 22-29 have been amended. Claims 10, 14 and 15 have been deleted. Claims 1-9, 11-12, 16-29 are pending. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons that follows. Any rejection not reiterated in this action have been withdrawn as being obviated by the amendment of the claims.

This action is made FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Previous rejections

3. The claimed rejections under 35 U.S.C. 112 first paragraph directed to claims 1-9 and 16-21 as lacking adequate written description are maintained and discussed below. The claim rejection under 35 USC 112 second paragraph directed to claims 2-8, 10-12, 14-19 are withdrawn in view of Applicant's amendments. The prior art rejection under 35 USC 102(b) direct to claims 2, 4-8 as being anticipated by Croce et al. is maintained and discussed below.

Claim Rejections - 35 USC § 112: Lack of adequate Written Description

4. Claims 1-9, 16-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed invention is drawn to a pair of nucleic acid probes and kit having comparable size, said size being selected from the group consisting of from 1 to 100 kb, from 1 to 10 kb, 7 to 15 kb, 10 to 20 kb, 10 to 30 kb, 20 to 40 kb, 30 to 50 kb, 40 to 60 kb, 50 to 70 kb, 60 to 80 kb, 70 to 90 kb and 80 to 100 kb and flanking a potential breakpoint in a single chromosome, each of said pair of probes being labeled with at least one different reporter molecule such that a split single arises after a break within said potential breakpoint. The claims are also drawn to a pair of nucleic acid probes of comparable size, said size being selected from the group consisting of from 1 to 100 kb, from 1 to 10 kb, 7 to 15 kb, 10 to 20 kb, 10 to 30 kb, 20 to 40 kb, 30 to 50 kb, 40 to 60 kb, 50 to 70 kb, 60 to 80 kb, 70 to 90 kb and 80 to 100 kb and flanking a potential breakpoint in a single chromosome, which pair of nucleic acid probes hybridize to a nucleic acid molecule at a genomic distance of from about 50 kb to nor more that 100 kb. The claimed pair of nucleic acid probes having comparable size and flanking a potential breakpoint in a single chromosome encompass a large genus of nucleic acid sequence not adequate described or disclosed in the specification. The specification and claims focus only on the location of the probe pairs but do not describe or disclose all possible sequences that can potentially flank a potential breakpoint. Likewise the specification or claims do not describe the large genus of unknown sequences that are capable of flanking a potential breakpoint. The specification do not describe any specific pair of nucleic acid sequences that flank all possible breakpoints in a single chromosome. A representative number of species for each genus must be disclosed to meet the written description requirement of

112, first paragraph. As set forth by the Court in *Vas Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date Applicant was in possession of the claimed invention. Absent a written description disclosing a representative number of the species as claimed in claims 1-10, 16-21 of the specification fails to show that Applicant was, in fact, "in possession of the claimed invention" at the time the application for patent was filed.

5. Applicant traverses the rejection on the following grounds: Applicant states that the claim have been amended to recite a pair of nucleic acid probes for detection of chromosomal aberrations in hematological malignancies. Applicant states that this limitation is supported in the specification as filed. Applicant states that the specification further illustrates that, at the time of filing, Applicant were referring to a multitude of chromosomal aberrations in hematological malignancies for which sufficient sequence information was publicly known. Applicant request the rejection be withdrawn.

6. The arguments filed in Paper No. 25 have been thoroughly reviewed and considered but they are not found persuasive for the reasons that follows: In response to Applicant's argument that the limitation ""for detection of chromosomal aberrations in hematological malignancies" indicates that at the time of filing, applicants were referring to a multitude of chromosomal aberrations in hematological malignancies for which sufficient sequence information was publicly known", it is noted that a recitation of the intended use of the claimed invention must result in a structural

difference in the claimed invention in order to establish patentably of the claimed invention. In a claim drawn to a process of making, the intended use must result in a manipulative difference of the intended use to carry any patentable weight. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). To reiterate the prior Office Action, the specification and claims only focus on the location of the claimed probes pairs but do not describe or disclose all possible sequences that can potentially flank a potential breakpoint of a chromosome. The claim invention encompasses a large genus of nucleic acid sequences not adequately described or disclosed. Applicant's arguments are not sufficient to overcome the claim rejection under 35 USC 112 first paragraph. Accordingly, the rejections are maintained.

Claim Rejections - 35 USC § 102

6. Claims 2, 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Croce (5,567,586, October 22, 1996). Regarding claim 2, Croce teaches a pair of nucleic acid probes of comparable size consisting of 0.1 to 10 kb, 0.5 to 5 kb, 0.8 to 3.5 kb (col. 5, lines 1-5) and flanking a potential breakpoint in a single chromosome (col. 7, lines 43-45) which nucleic acid hybridize to a nucleic acid molecule at a genomic distance greater than 3.5 kb (col. 5, lines 10-13).

Regarding claims 4 and 5, Croce et al. teach wherein the pair of probes are labeled with at least reporter molecule a fluorescent marker, such as biotin (col. 65-66).

Regarding claims 6 and 7, Croce et al. teach wherein the pair of probes hybridizes to a single corresponding nucleic acid molecule wherein the nucleic acid molecule is at least a fragment of a chromosome (col. 7, lines 41-45).

Regarding claim 8, Croce et al. disclose wherein the chromosome is not aberrant (col. 7, lines 45-47). Therefore, the claimed invention of claims 2, 4-8 are anticipated by the reference of Croce.

7. Applicant traverses the rejection on the following ground: Applicant states that the claims are not anticipated by Croce because Croce does not relate to hematological malignancies, but rather to solid tumors. Applicant request the rejection be withdrawn.

8. The arguments have been thoroughly reviewed but are not found persuasive for the reasons that follows: In regards to Applicant's arguments that the Croce reference does not relate to hematological malignancies but rather to solid tumors, it is noted that the limitation "for detection of chromosomal aberrations in hematological malignancies" is a recitation of the intended use of the claimed invention but does not result in a structural different between the claimed invention and prior art. MPEP states that a recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*,

152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Applicant's arguments do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections. Accordingly, the prior art rejection under 35 U.S.C. 102 is maintained.

New Ground(s) of Rejections

THE NEW GROUND(S) OF REJECTIONS WERE NECESSITATED BY APPLICANT'S AMENDMENT OF THE CLAIMS:

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

10. Claims 23-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Claims 23-29 lack proper antecedent basis for "the pair of nucleic acid probes" because claim 22 from which the claims depend recited a method but does not recite a pair of nucleic acid probes. It is suggested amending claims by changing "The pair of nucleic acid probes" to --The method--.

Conclusion

11. Claims 1-9, 16-21, 23-29 are rejected. Claims 11, 12 and 22 are allowable. Claims 23-29 are free of the prior art and will be allowed upon correcting 35 USC 112 second paragraph issues.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 9:30 am to 6:30 pm and Friday 9:30 am to 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group's receptionist at (703) 308-0196.

Cynthia B. Wilder, Ph.D.

May 12, 2003

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

5/14/03